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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Masao Ieno

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EXAMINER

SIMMONS WILLIS, TRACEY A

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

08/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,633	<b>Applicant(s)</b> IENO ET AL.	
	<b>Examiner</b> TRACEY SIMMONS WILLIS	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8,10 and 15-22 is/are pending in the application.
- 4a) Of the above claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-8 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01062006:01312007</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

Applicant's amendments filed March 31, 2009 to claims 1, 7, and 10 have been entered. Claims 3-5, 9, and 11-14 have been cancelled. Claims 1-2, 6-8, 10, and 15-22 remain pending in the current application, of which claims 1-2, 6-8, and 10 are being considered on their merits. Claims 15-22 remain withdrawn from consideration at this time. References not included with this Office action can be found in a prior action. Any rejections or objections of record not particularly addressed below are withdrawn in light of the claim amendments and applicant's comments.

### ***Information Disclosure Statement***

Applicant has submitted several documents as listed on the information disclosure statement (IDS) forms that do not have an English translation provided therewith; and furthermore, do not present a statement of relevance listed in the IDS letter. These documents have not been considered by the examiner.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities:

- Line 1 of the claim should read "A sustained-release" as opposed to "Sustained-release", and
- Line 1 of the claim should read as "for an amino acid derivative" or "for amino acid derivatives".

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- Line 5 of the claim recites the term "basic functional group(s)". Examiner suggests adding the term "pH" after the word basic to further clarify that the functional groups behave as bases and are not reflective any type of functional group.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Line 3 of the instant claim uses the term "the polymer in is in the form of a fiber"; however the instant Specification discloses "a fiber structure containing said polymer" (pg 3) and a fiber-shaped polymer (pg 23). The recited polymer does not appear to have support in the instant Specification and the amendment to the claim appears to constitute new matter, as a polymer in the form of a fiber is different from a fiber containing a polymer and a fiber-shaped polymer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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**Claims 1-2, 6-8, and 10 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 refers to an “amino acid derivative” with the formula [I] within its molecule. One of ordinary skill in the art would not be able to ascertain how an amino acid derivative could be represented by formula [I] as provided, as there are undefined groups on either end of the structure.

Because claims 2, 7, 8, and 10 depend from indefinite claim 1 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

Claim 6 lists the derivatives of claim 1 as amino acids themselves, which would not include the additional undefined groups on the amine and carbonyl ends as shown in formula [I]. One of ordinary skill would not be able to ascertain how an amino acid can represent the definition of the derivative as recited in claim 1. Clarification is required.

### ***Response to Arguments***

Applicant’s arguments, with respect to 35 U.S.C. 112p2 over claim 2 have been carefully considered and are persuasive. The 35 U.S.C. 112p2 rejection of claim 2 has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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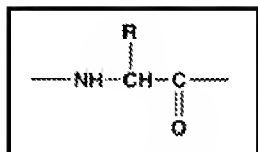
**Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,508,164 (1996, Kausch et al) as evidenced by Molecular Biology of the Cell, 4<sup>th</sup> Edition (2002, Alberts et al).**

Claim 1 recites a sustained-release polymer for an amino acid derivative containing formula [I] in its molecule, the polymer is in the form of a fiber and contains an acidic group ionically bonded to the amino acid derivative.

Kausch teaches isolated chromosomes that contain histone within the DNA structure [col 18, lines 19-30 and col 7, lines 23-24]. The chromosomes are threadlike structures of DNA (fibers containing acidic groups) and proteins, such as histone which contain amino acids with basic pH functional groups meeting the limitation of the claim. The peptides contain the recited structure of formula [I] as evidenced by Alberts [see attachment, Fig 3-1].

**Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Application Publication No. JP 2002-284619 (Imori et al) as evidenced by Plastics Materials and Processes (2003, Harper et al).**

The instant claims recite a sustained-release polymer, in the form of a fiber,

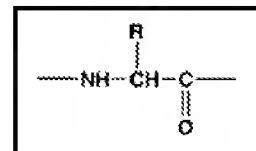


further characterized in that the polymer contains an acidic group that is ionically bonded to an amino acid derivative of formula [I], wherein R is a

group having one or more basic functional groups. The claims further recite the amino acid derivative to be selected from arginine, lysine, and histidine, and the sustained-release polymer to contain a carboxyl group as the acidic group.

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Imori teaches of anionic polymers with carboxyl group content (of carboxylic acid) that act on amino acids with basic pH functional groups such as lysine, arginine, and histidine [pg 4, pars 10 and 11]. *claims 1, 6, and 8* The amino acid is mixed with anionic polymers so the carboxyl groups of the polymers neutralize the amino acid containing basic functional groups prior to mixing in the cystine derivative [pg 2, par 5]. Anionic polymers include (meth)acrylic acid [pg 4, par 11].



While Imori is silent to the polymer being a fiber, one of ordinary skill in the art would have found the (meth)acrylic acid polymer to constitute a fiber as evidenced by Harper et al [pg 7].

### ***Response to Arguments***

In Applicant's remarks (35 U.S.C. §102 (b) with regard to claims 1-14), Applicant alleges that Hansen does not teach of fibers as defined in the specification, but of particles, and fibers disclosed in Hansen is cellulose and does not meet the limitations of the claims (pg 6).

Applicant's arguments with respect to 35 U.S.C. §102 (b) with regards to claims 1, 2, 6-8, and 10, have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1, 2, 6, 8, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Application Publication No. JP 2002-284619 (Imori et al) in view of U.S. Patent 5,853,879 (1998, Takayima et al).**

The instant claims recite a sustained-release polymer in the form of a fiber containing an amino acid derivative of formula [I], such as lysine, arginine, and histidine, ionically bonded to the carboxyl acidic groups of the polymer. The claims further cite functional limitations related to elution rates of the polymer and that the polymer has a cross-linked structure formed by reaction of a nitrile group with hydrazine.

Imori teaches cosmetics which blend a cystine derivative and a basic amino acid without generating an unpleasant smell. The amino acid is mixed with the carboxyl group of anionic polymers to neutralize the basic amino acid prior to mixing in the cystine derivative [pg 2, par 5]. *claims 1 and 6* Anionic polymers include (meth)acrylic acid [pg 4, par 11]. Basic amino acids include L-arginine, L-lysine, and L-histidine [pg 4, par 10]. *claim 8*

Imori does not specifically teach the eluting rate ( ) of the amino acid derivative when polymer is dipped in artificial sweat of 10% or more and five times or more that of the eluting rate ( ) of the amino acid derivative when the polymer is dipped in pure water. Imori also does



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not teach polymers containing acidic group to have a crosslinked structure formed by reaction of a nitrile group with a hydrazine compound.

Takayima teaches of high moisture-absorbing and moisture-releasing fibers of acrylic fibers crosslinked with hydrazine compounds such as hydrazine hydrate [col 1, lines 16-17, 36-37, and 56-59]. *claim 10*

One of ordinary skill in the art at the time of the invention would have been motivated to use acrylic fibers of Takayima in the invention of Imori with a reasonable expectation of success as the functional group and the polymer type (acrylic acid) are the same as that of Imori.

While the property of the elution rate is not explicitly taught in the prior art (*claim 2*), one of ordinary skill in the art would have expected the elution rate properties to have been as recited as the components of the polymer for release of the amino acid was taught in the prior art, and a product cannot be separated from its properties. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Therefore the invention would have been *prima facie* obvious at the time it was made.

**Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Imori in view of Takayima as applied to claims 1, 2, 6, 8, and 10 above, and further in view of U.S. Patent 7,273,501 (2007, Nakashima et al).**

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The instant claim recitations are as stated above. The instant claim further recites the functional limitation of the polymer to have a saturated hygroscopic degree of 20% at 20°C and 65% relative humidity.

The combined teachings of Imori and Takayima are relied upon above.

Neither reference teaches the polymer containing acidic group having a saturated hygroscopic degree of 20% at 20°C and 65% relative humidity.

Nakashima teaches of moisture absorptive and desorptive fibrous structures with a saturated index of 10% or more and 65% relative humidity [col 3, lines 20-24]. The fibers are acrylic fibers (containing carboxyl acidic group) [col 3, line 29], crosslinked by hydrazine compounds [col 4, lines 17-20] such as hydrazine sulfate [col 7, line 32].

One of ordinary skill in the art at the time of the invention would have been motivated to use the fibers of Nakashima in the invention of Imori with a reasonable expectation of success, as the fibers contain the carboxylic functional group (acrylic acid), as the same polymer type used in Imori for interaction with the amino acids, and appear to be the same fiber type as Takayima. Nakahima further teaches that said acrylic acid fibers possess the desired hygroscopic properties as recited.

Therefore the invention would have been *prima facie* obvious at the time it was made.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRACEY SIMMONS WILLIS whose telephone number is

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(571)270-5861. The examiner can normally be reached on Mondays to Fridays from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. S.W./

Examiner, Art Unit 1619

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638